REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested. Pursuant to 37 CFR § 1.121, attached as Appendix A is a Version With Markings to Show Changes Made.

The rejection of claims 11 and 15 under 35 U.S.C. § 112, first paragraph, for lack of enablement is respectfully traversed in view of the attached Declaration of Ray Wu.

The rejection of claims 1-18 under 35 U.S.C. § 112, second paragraph, for indefiniteness is respectfully traversed in view of the above amendments and the following remarks.

With regard to the rejection of claims 1 and 5, it is the position of the U.S. Patent and Trademark Office ("PTO") that the terms "minimal promoter" and "shortened promoter" render the claims indefinite. Applicants respectfully disagree.

Definiteness of claim language must be analyzed in view of "(A) The content of the particular application disclosure; (B) The teaching of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made." MPEP, § 2173.02.

The terms "minimal promoter" and "shortened promoter" are well known terms in the art and are used, for example, in Su et al., "Dehydration-Stress-Regulated Transgene Expression in Stably Transformed Rice Plants," Plant Physiol., 117:913-922 (1998), Shen et al., "Functional Dissection of an Abscisic Acid (ABA)-Inducible Gene Reveals Two Independent ABA-Responsive Complexes Each Containing a G-Box and a Novel *cis*-Acting Element," The Plant Cell, 7:295-307 (1995), and Shen et al., "Modular Nature of Abscisic Acid (ABA) Response Complexes: Composite Promoter Units That Are Necessary and Sufficient for ABA Induction of Gene Expression in Barley," The Plant Cell, 8:1107-1119 (1996). As used in the art and as used in the present application, the term "shortened promoter" is understood to describe a truncated promoter which still retains its promoter activity. Similarly, a "minimal promoter" is a "shortened promoter" where the minimal promoter is necessary and sufficient for promoter activity, but does not contain at least some of the regulatory elements of the full promoter sequence. Accordingly, this rejection of claims 1 and 5 under 35 U.S.C. § 112, second paragraph, is improper and should be withdrawn.

With regard to the rejection of claim 12, it is the PTO's position that the term "associated" in claim 12 is unclear. Applicants respectfully disagree.

As described above, definiteness of claim language must be analyzed in view of "(A) The content of the particular application disclosure; (B) The teaching of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made." MPEP, § 2173.02.

The specification of the above-identified application discloses that introduction of a plasmid containing a DNA molecule that increases tolerance to salt stress and drought stress can be achieved by particle bombardment, by propelling inert or biologically active particles at the cells under conditions effective to penetrate the outer surface of the cell and to be incorporated within the interior thereof (see Specification at page 15, lines 4-13). When inert particles are utilized, the plasmid can be introduced into the cell by coating the particles with the plasmid containing the heterologous DNA (see Specification at page 15, lines 13-15). Alternatively, the target cell can be surrounded by the plasmid so that the plasmid is carried into the cell by the wake of the particle (see Specification at page 15, lines 15-16). Biologically active particles (e.g., dried bacterial cells containing the plasmid and heterologous DNA) can also be propelled into plant cells (see Specification at page 15, lines 17-18). Thus, one of ordinary skill in the art would be able to determine the nature of the association between the plasmid and the particles, when the claims are read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claims. Accordingly, this rejection of claim 12 under 35 U.S.C. § 112, second paragraph, is improper and should be withdrawn.

The rejection of claims 1-4, 7, and 9 under 35 U.S.C. § 102(b) as anticipated by Wu et al., "Production of Transgenic Rice Plants that are Resistant to Insect Pests and Fungal Diseases or to Water and Salt Stress," General Meeting of the International Program on Rice Technology, abstract 113 (1997) ("Wu I") is respectfully traversed.

Wu I is an abstract that discloses using constitutive or ABA-inducible promoters in conjunction with water stress or salt stress tolerance genes to produce water stress or salt stress tolerant transgenic rice plants.

It is the PTO's position that Wu I teaches the production of water stress or salt stress tolerant transgenic rice plants and the use of constitutive or ABA-inducible promoters. Although Wu I does not explicitly teach an ABRC unit, or salt stress or drought stress

induction of an expression cassette, the PTO argues that such features would be inherent in an ABA-inducible promoter.

Wu I neither discloses nor suggests an expression cassette comprising at least one ABRC unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and drought stress in plants, as required by the claims of the present application. Moreover, Wu I does not provide an enabling disclosure of the ABRC (ABA-response complex) unit, as required by the claims of the present application. In particular, as Wu I includes no disclosure relating to an ABRC unit, it cannot provide an enabling disclosure of the ABRC unit, as claimed in the present application. Accordingly, the rejection based on Wu I is improper and should be withdrawn.

The rejection of claims 1-9 under 35 U.S.C. § 102(b) as anticipated by Cheng et al., "Development of Transgenic Cereal Crop Plants that are Tolerant to High Salt, Drought and Low Temperature," Frontiers in Biology: The Challenges of Biodiversity, Biotechnology and Sustainable Agriculture, Chou and Shao (eds.), Academia Sinica, Taipei (1998) ("Cheng") is respectfully traversed.

In particular, Cheng does not qualify as Section 102(b) prior art. More specifically, as set forth in a letter from Chang-Hung Chou, editor of Cheng, attached hereto as Exhibit A, Cheng was published in July 1998. Three volumes of the publication were provided to Chang-Hung Chou on July 3, 1998. These volumes were used internally to close out the budget at Academia Sinica. The remaining volumes of the publication were sent to Chang-Hung Chou on July 13, 1998. These volumes were then distributed to the public after July 13, 1998. The present application was filed on July 9, 1999. Since Cheng was made available to the public less than a year before the present application's filing date, Cheng cannot qualify as Section 102(b) prior art.

Moreover, as demonstrated in the attached Declaration of Ray J. Wu ("Wu Declaration"), Cheng is not prior art under 35 U.S.C. § 102(a). The present invention was conceived solely by Ray J. Wu and Tuan-Hua David Ho (Wu Declaration ¶ 4). Further, Weizhong Cheng, Jin Su, Baochen Zhu, and T.L. Jayaprakash, co-authors of Cheng, did not contribute to the conception of the present invention (Wu Declaration ¶¶ 5-8). Weizhong Cheng was a post-doctoral fellow in the laboratory of Ray J. Wu at the time Cheng was prepared. Weizhong Cheng performed some of the experiments described in Cheng under the supervision of Ray J. Wu. Jin Su was also a post-doctoral fellow in the laboratory of Ray

J. Wu at the time Cheng was prepared. Jin Su also performed some of the experiments described in Cheng under the supervision of Ray J. Wu. Baochen Zhu was a graduate student in the laboratory of Ray J. Wu at the time Cheng was prepared. Baochen Zhu performed some of the experiments described in Cheng under the supervision of Ray J. Wu. T.L. Jayaprakash was a post-doctoral fellow in the laboratory of Ray J. Wu at the time Cheng was prepared. T.L. Jayaprakash performed some of the experiments described in Cheng under the supervision of Ray J. Wu. In view of the Wu Declaration, it is clear that Cheng is not the work of "another", under 35 U.S.C. § 102(a). See In re Katz, 687 F.2d 450, 215 USPQ 14 (C.C.P.A. 1982). As a result, Cheng cannot be Section 102(a) prior art with respect to the claimed invention.

Accordingly, Cheng cannot be prior art with respect to the claimed invention, and the rejection based on Cheng is improper and should be withdrawn.

The rejection of claims 1-18 under 35 U.S.C. § 103(a) as being unpatentable over either of Wu I or Cheng in view of Applicants' admitted prior art is respectfully traversed in view of the above remarks.

The rejection of claims 1-18 under 35 U.S.C. § 103(a) as being unpatentable over Xu et al., "Expression of a Late Embryogenesis Abundant Protein Gene, *HVA1*, from Barley Confers Tolerance to Water Deficit and Salt Stress in Transgenic Rice," Plant Physiol., 110:249-257 (1996) ("Xu") in view of Shen et al., "Modular Nature of Abscisic Acid (ABA) Response Complexes: Composite Promoter Units That Are Necessary and Sufficient for ABA Induction of Gene Expression in Barley," The Plant Cell, 8:1107-1119 (1996) ("Shen"), further in view of Applicant's admitted prior art is respectfully traversed.

Xu discloses introducing the *HVA1* gene from barley into rice cells using the biolistic-mediated transformation method to generate transgenic rice plants. Xu teaches that expression of the *HVA1* gene regulated by the rice actin 1 gene promoter led to high-level, constitutive accumulation of the HVA1 protein in the transgenic rice plants which exhibited significantly increased tolerance to water deficit and salt stress.

Shen discloses the sequence for an abscisic acid response complex ("ABRC") from a barley *HVA1* gene. Shen teaches that the combination of different ACGT-boxes and coupling elements leads to the formation of ABRCs with different transcription strengths and suggests that the disclosed synthetic promoters capable of conferring different levels of ABA

induction could be used to drive the expression of genes that would enhance plant stress tolerance.

It is the PTO's position that it would have been obvious to a person of ordinary skill in the art to use a minimal promoter operably linked to an ABRC, as taught by Shen, to express a DNA molecule that increases tolerance to salt stress or drought stress in plants, as taught by Xu, for the purpose of conferring salt stress or drought stress tolerance to a monocot plant. Applicants respectfully disagree.

A proper *prima facie* showing of obviousness requires the PTO to satisfy three requirements. First, the prior art relied upon, coupled with knowledge generally available to one of ordinary skill in the art, must contain some suggestion which would have motivated the skilled artisan to combine or modify references. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the PTO must show that, at the time the invention was made, the proposed modification had a reasonable expectation of success. See Amgen v. Chugai Pharm. Co., 927 F.2d 1200, 1209, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Finally, the combination of references must teach or suggest each and every limitation of the claimed invention. See In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The PTO has failed to show any reasonable expectation of success. In particular, the PTO's position appears to be an impermissible obvious-to-try standard. In re Dow Chemical Co., 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). An obvious-to-try situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result. In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990). Merely offering a scientist an opportunity to do many months of experimentation is not sufficient to show obviousness. Although Shen suggests that the disclosed synthetic promoters capable of conferring different levels of ABA induction could be used to drive the expression of genes that would enhance plant stress tolerance, that reference provides no reasonable expectation of success for a method for conferring tolerance to salt stress and drought stress in a monocot plant comprising transforming the monocot plant with an expression cassette comprising at least one ABRC unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and

drought stress in plants, as required by the claims of the present application. Accordingly, the rejection based on Xu and Shen is improper and should be withdrawn.

Claims 1-18 are provisionally rejected under 35 U.S.C. § 103(a) for obviousness over copending U.S. Patent Application Serial No. 09/107,201 to Wu et al. ("'201 application"). Applicants request that this rejection be held in abeyance until one of the pending applications is issued.

Claims 1-18 are provisionally rejected under 35 U.S.C. § 103(a) for obviousness over copending U.S. Patent Application Serial No. 09/339,364 to Wu et al. ("'364 application"). Applicants request that this rejection be held in abeyance until one of the pending applications is issued.

The rejection of claims 1-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 5,981,842 to Wu et al. ("Wu II") is respectfully traversed.

Claims 1-7 and 10 of Wu relate to a method of producing a cereal plant cell or protoplast for regeneration of a water stress or salt stress tolerant cereal plant by transforming a cereal plant cell or protoplast with a nucleic acid encoding a group 3 late embryogenesis abundant protein and a method of increasing tolerance of a cereal plant to water stress or salt stress conditions by increasing levels of a late embryogenesis abundant protein by transforming the plant with a nucleic acid encoding a group 3 late embryogenesis abundant protein.

It is the PTO's position that the use of ABRC units, minimal promoters, and *Agrobacterium*-mediated transformation in the methods of the instant invention would have been an obvious optimization of design parameters, because ABRC units, minimal promoters, and the use of *Agrobacterium*-mediated transformation were known in the art at the time of Applicants' invention. Accordingly, the PTO argues that claims 1-18 of the present application are not patentably distinct from claims 1-7 and 10 of Wu II. Applicants respectfully disagree.

In particular, claims 1-7 and 10 of Wu II neither disclose nor suggest "transforming the monocotyledonous plant with an expression cassette comprising at least one abscisic acid response complex unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and drought stress in plants," as required by the claims of the present application, as amended. Moreover, to the extent the PTO is combining the

disclosure of claims 1-7 and 10 of Wu II with other cited art in the outstanding office action, applicants respectfully request that such a combination be identified by the Examiner, so that applicants can properly respond. Accordingly, this rejection is improper and should be withdrawn.

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5, 11-12, 15, 46-55, and 72 of the '201 application. Applicants request that this rejection be held in abeyance until one of the pending applications is issued.

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of the '364 application. Applicants request that this rejection be held in abeyance until one of the pending applications is issued.

In view of the all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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Nov. 22, 2002 Date	Ruth R. Smith

Appendix A

Version With Markings to Show Changes Made

In reference to the amendments made herein to claims 1-18, additions appear as underlined text, while deletions appear as bracketed text, as indicated below:

In The Claims:

1. (Amended) A method for conferring tolerance to salt stress and drought stress in a monocotyledonous [monocot] plant comprising:

transforming the monocotyledonous [monocot] plant with an expression cassette comprising at least one abscisic acid response complex [ABRC] unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and drought stress in plants, wherein the at least one abscisic acid response complex [ABRC] unit, the minimal promoter, and a DNA molecule are operably linked together to permit expression of the DNA molecule, and

expressing the DNA molecule in the monocotyledonous plant to confer tolerance to salt stress and drought stress in the plant.

2. (Amended) The [A] method according to claim 1, wherein the monocotyledonous [monocot] plant is selected from the group consisting of rice, wheat, maize, barley, oat, rye, millet, and sorghum.

3. (Amended) The [A] method according to claim 2, wherein the monocotyledonous [monocot] plant is rice.

4. (Twice-Amended) The [A] method according to claim 1, wherein the DNA molecule that increases tolerance to salt stress and drought stress is selected from the group consisting of a Δ^1-pyrroline-5-carboxylate synthetase gene, *P5CS*-129A, *Hva1*, COR47, a mannitol 1-P-dehydrogenase gene, a gene for the biosynthesis of polyamines, and a gene for the biosynthesis of glycine betaine, trehalose, D-ononitol or fructans.

5. (Amended) The [A] method according to claim 1, wherein the minimal promoter is Act1-100 of rice, a shortened α-amylase promoter of barley or rice, a shortened maize ubiquitin promoter, or a shortened CaMV 35S promoter.

6. (Amended) The [A] method according to claim 1, wherein the at least one abscisic acid response complex [ABRC] unit is from a barley *HVA22* gene or a barley *HVA1* gene.

7. (Amended) The [A] method according to claim 1, wherein the expression cassette comprises up to four of the abscisic acid response complex [ABRC] units operably linked together.

8. (Amended) The [A] method according to claim 1, wherein the expression cassette further comprises:

a DNA sequence coding a selectable marker.

9. (Amended) The [A] method according to claim 1, wherein the expression cassette is salt stress or drought stress inducible.

10. (Amended) The [A] method according to claim 1, wherein said transforming comprises:

propelling particles at cells of the monocotyledonous [monocot] plant under conditions effective for the particles to penetrate into the cell interior and

introducing a plasmid comprising the at least one abscisic acid response complex [ABRC] unit, the minimal promoter, and the DNA molecule that increases tolerance to salt stress and drought stress in plants into the cell interior.

11. (Amended) The [A] method according to claim 10, wherein the plasmid is selected from the group consisting of pJS112, pJP21, and pJPM001.

12. (Amended) The [A] method according to claim 10, wherein the plasmid is associated with the particles, whereby the plasmid is carried into the cell interior together with the particles.

13. (Amended) The [A] method according to claim 10, wherein the plasmid surrounds the cell and is drawn into the cell interior with the particles.

14. (Amended) The [A] method according to claim 1, wherein said transforming comprises:

contacting tissue of the monocotyledonous [monocot] plant with an inoculum of a bacterium of the genus *Agrobacterium*, wherein the bacterium is transformed with a plasmid comprising the at least one abscisic acid response complex [ABRC] unit, the minimal promoter, and the DNA molecule that increases tolerance to salt stress and drought stress in plants.

15. (Amended) The [A] method according to claim 14, wherein the plasmid is selected from the group consisting of pJS112, pJP21, and pJPM001.

16. (Amended) The [A] method according to claim 14, wherein the bacterium of the genus *Agrobacterium* is *Agrobacterium tumefaciens*.

17. (Amended) The [A] method according to claim 14, wherein the tissue is selected from protoplasts, cells, or calli derived from mature embryo or immature embryo of rice, wheat, maize, barley, oat, rye, millet, or sorghum.